



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BS

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/873,645 | 06/04/2001 | Paul D. Taylor | P-633 | 4460 |
| 25732 | 7590 | 08/09/2005 | EXAMINER | |
| KEITH JOHNSON, ESQ. TRANSGENOMIC, INC. 12325 EMMETT STREET OMAHA, NE 68164 | | | CLOW, LORIA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/873,645 | TAYLOR ET AL. | |
| | Examiner Lori A. Clow, Ph.D. | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 May 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 13-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 13-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10 May 2005.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Applicants' arguments, filed 10 May 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 13-16 are currently pending.

Information Disclosure Statement

The Information Disclosure Statement filed 10 May 2005 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

Claim Rejections - 35 USC § 112-2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites "a system for computer implemented adjustment...for grouping of the plurality of chromatographic elution profiles method". It is unclear what is intended by this recitation. Does Applicant intend that the system comprises an elution profile method? Does Applicant intend grouping of a plurality of chromatographic elution profile methods?

Clarification is requested.

Art Unit: 1631

Claim 13, step (c) recites “within said span” and “said factor”. What span and what factor are intended? Does Applicant intend “within said time span” or some other span. Does Applicant intend “said slope factor” or some other factor? Clarification is requested.

Claim 13 further recites “wherein the computer receives a set of data”. It is unclear whether Applicant intends a method step or a limitation of the system. If the later then it is unclear as to whether the data received actually limits the computer system or does Applicant intend that the apparatus be limited only to the method performed by the processor? Clarification is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues the following:

“The instant method solves the problem of variations in samples by using a computer to adjust signal and time data to correct such variations so that chromatographic elution profiles achieve

Art Unit: 1631

values useful for grouping based on their shape or pattern. The shape or pattern of elution profiles is determined by number, height, width, symmetry, and retention time peaks. Chromatograms having matching profiles are subsequently grouped together to detect the presence of mutations in the DNA sample being analyzed. The disclosed method has utility in analyzing a plurality of samples, including test fragments having previously uncharacterized SNPs or standard fragments having a known sequence, to generate chromatographic profiles which are grouped. A test fragment profile that matches a group with a known SNP is sequenced to confirm the site variation and test fragments which yield a profile that does not match one of the existing groups is characterized as a new mutation”.

This is not persuasive. First, the rejection set forth is based upon enablement (35 USC 112, 1st paragraph) and not on utility (35 USC 101). There is no rejection with regard to whether the instant claims have utility. Rather, the rejection states that the instant claims lack enablement, as set forth previously.

Secondly, the instant claims do not recite any limitations that include mutations or SNPs. It is maintained that one of skill in the art would not know how to use the data generated by this system to group the elution profiles for a particular purpose. The instant claims are generic and say nothing about the comparison or matching of SNPs or test sequences such that mutations are identified. The claims are not directed to SNP or mutation data. One of skill in the art would have to guess at what groups to use, and therefore would not know how to group chromatographic profiles, as previously set forth. Therefore, the Examiner maintains that the claims lack enablement, as set forth in the previous Office Action.

Art Unit: 1631

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

August 4, 2005

Lori A. Clow, Ph.D.

Art Unit 1631

Lori A. Clow

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
8/4/05